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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BAUSCH, SARAE L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,898

Applicant(s)

ASTATKE, MEKBIB

Examiner

Sarae Bausch

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 11-23 and 34-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/04, 04/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-10 and 24-33 in the reply filed on 09/08/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that applicants elected group I. Group I of the restriction requirement mailed 08/04/2006 is claims 1-10 and 24-33, see page 2 of the restriction mailed 08/04/2006.

2. Claims 11-23 and 34-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/08/2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-27, 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a). Regarding claims 26-27 and 29, the phrase "derivatives and analogs thereof" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "derivatives and analogs thereof"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

(b). Claim 29 recites the limitation "the ribonucleotide" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 29 is dependent from claim 27. Claim 27 recites the deoxynucleotide and does not recite a ribonucleotide and therefore lacks antecedent basis.

(c). The recitation of "NTA" in claim 30 and 31 renders the claim indefinite. NTA is not defined in the claims and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Claim 31 recites wherein the NTA is α -N,N-bis-carboxymethyl lysine, however the specification does not define NTA as α -N,N-bis-carboxymethyl lysine and it is unclear if the term NTA is being defined as α -N,N-bis-carboxymethyl lysine in the claim. Furthermore, if α -N,N-bis-carboxymethyl lysine is defining the term NTA, it is unclear how claim 31 further limits claim 30.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6, 9-10, 24-30, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Stanley et al. (US 2001/0047077 A1, published Nov 29, 2001).

With regard to claim 1 and 24, Stanley et al. teach nucleic acid analogs having a chelation functionality (see paragraph 1, page 1). Stanley et al. teach a PNA compound (nucleic acid) covalently bonded to a nucleotide and a chelating moiety (see paragraph 16 and 34). Stanley et

al. teach the chelating moiety is capable of binding at least on metal ion by chelation (see paragraph 8).

With regard to claim 2, Stanley et al. teach a PNA compound (nucleic acid) with multiple chelating moieties covalently bonded (see paragraph 18).

With regard to claim 3-5, 32-33, Stanley et al. teach a PNA compound covalently bonded to histidines chelated to a Ni-NTA column (nucleic acid covalently bonded to a chelating agent having an affinity for a transition metal, Ni) (see paragraph 92).

With regard to claim 3, 6 and 9, Stanley et al. teach a labeled nucleic acid analog (nucleic acid) chelated to a transition metal as a label or a labeling moiety linked via a metal ion chelated to said chelating moiety. Stanley et al. teach a radiolabel such as indium (claim 6) or a fluorescent label such as europium or terbium (claim 9) (see paragraph 56).

With regard to claim 10, Stanley et al. teach a labeled nucleic acid analog with a chelating moiety and reporter ligand wherein a preferred reporter ligand is biotinoyl (see paragraph 116).

With regard to claim 25-29, Stanley et al. teach a nucleic acid analog covalently bonded to oligodeoxyribonucleotides and oligoribonucleotides (see paragraph 34). Stanley et al. teach a histidines (chelating agent) covalently bonded to a PNA with the following sequence TGTACGTCACAACTA (claim 26, 27, and 29) (see paragraph 72). It is noted that the rejection is being applied to claim 29 based on the interpretation that the claim is limited to a nucleotide-chelating agent wherein the nucleotide is a ribonucleotide.

With regard to claim 30, Stanley et al. teach a chelating moiety of aminotriacetic acid (NTA).

7. Claims 1, 24, and 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. (US Patent 4024241, published May 17, 1977).

Levy et al. teach polyriboinosinic-polyribocytidylic-poly-L-lysine carboxymethylcellulose complex (claim 1, 24, 30-31) (see column 2, lines 32-35). Levy et al. teach a nucleic acid, polyriboinosinic-polyribocytidylic, covalently bonded to a chelating agent, carboxymethyl (claim 30) which has affinity for transition metal ion, Ni (claims 32-33). Levy et al. teach the nucleotide is a ribonucleotide consisting of CTP and derivatives thereof (claim 28-29). It is noted that the rejection is being applied to claim 29 based on the interpretation that the claim is limited to a nucleotide-chelating agent wherein the nucleotide is a ribonucleotide.

8. Claims 1-10, 24-26, 30, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dervan et al. (US Patent 5998140, published Dec 7, 1999).

With regard to claim 1, 3-5, 24, 30, and 32-33, Dervan et al. teach chelating compounds on either terminus of an oligomer (nucleic acid covalently bonded to a chelating agent). Dervan et al. teach chelating compounds, such as EDTA, NTA (claim 31), where the chelating compound may chelate a metal atom, such as iron, cobalt, nickel, technetium, etc. (claim 3-5, 32-33) (see column 7, lines 33-40). In addition, Dervan et al. teach imidazole (chelating agent) covalently attached to a nucleotide (see column 23, lines 8-10).

With regard to claim 2, Dervan et al. teach two imidazole compounds covalently bound to a nucleotide (see column 23, lines 8-10).

With regard to claim 6-8, Dervan et al. teach a radioactive label on either the N or C terminus of the oligomer of any annular member of the heterocycle. Dervan et al. teach radioactive labels, such as tritium or C14, or the like can be used (see column 7, lines 10-20).

With regard to claim 9-10, Dervan et al. teach the oligomer may be linked to labels such as fluorescers (See column 7, lines 27-30) and may be combined with other labels, such as biotin (see lines 50-52).

With regard to claim 25-26, Dervan et al. teach a deoxynucleotide bound to a chelating agent, imidazole (see column 23, lines 8-10).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-10 and 24-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-11 and 13-16 of copending Application No. 11/191001 (‘001). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 and 24 is generic to all that is recited in claim 7-11, 13-16 of ‘001. Specifically, a conjugate having the structure of probe-NH-CO-Ar-hydrozone-Ar-CO-NH-[chel] of ‘001 anticipates the genus of a nucleic acid

covalently bonded to a chelating agent in the instant application. Furthermore, a chelating agent that is NTA and has an affinity for a transition metal, along with fluorescent labels and a biotin label is disclosed and claimed in '001 (claims 14-16 of '001).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

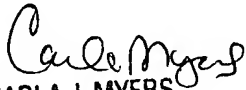
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

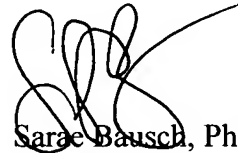
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CARLA J. MYERS
PRIMARY EXAMINER


Sarah Bausch, PhD.
Examiner
Art Unit 1634